



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,061	02/20/2007	Peisheng Cao	14556.0007USWO	7583

23552 7590 04/21/2008
MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
----------	--------------

1655

MAIL DATE	DELIVERY MODE
-----------	---------------

04/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,061	Applicant(s) CAO, PEISHENG	
	Examiner Patricia Leith	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-26 is/are pending in the application.
- 4a) Of the above claim(s) 8-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-4 and 6-26 are pending in the application, claims 20-26 being newly added in the most recent amendment submitted by Applicant on 2/7/08.

It is noted that claims 6 and 7 were inadvertently overlooked in the previous rejection. Claims 6 and 7 were fully examined on their merits along with claims 1-4 in this Office action. For this reason, new rejections have been placed over claims 6 and 7 which were not necessitated by Applicant's amendments to the claims. Therefore, this rejection is non-final.

Election/Restrictions

Claims 8-19 remain withdrawn from the merits being withdrawn without traverse in the reply filed on 10/22/07. Applicant attempts to rescind the original election and elect with traverse, however, the election is of record and is maintained, the original restriction requirement will not be withdrawn and Applicant's new traversals are thus rendered moot in light of the original election without traverse.

Newly submitted claims 20-26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 20 is directed toward the invention of Group II as this claim is further limiting the apparatus.

Claims 20-26 are directed toward a method for extracting via use of a particular extraction apparatus. While Applicant argues that:

In the present case, independent apparatus claim 8 includes features that are adapted to create conditions required by the process steps of claim 1. The apparatus is thus suitable for carrying out the process of claim 1 with technical relationship being present between the apparatus and process. Further, claim 8 has been amended to recite that the apparatus is "for carrying out the extraction method of claim 1". The pending claims thus meet the unity of invention requirement.
(p. 9, Remarks)

However, the claims still lack unity of Invention for at least two reasons: First, it is clear on the record that the invention of Group I lacks an inventive step over the cited prior art references which are maintained and/or newly stated *infra*. Thus, Unity of Invention is lacking because there is no 'special' technical feature found in the claims. Secondly, the alleged 'special' technical feature which is the apparatus, is not found and thus not required to practice the invention of Group I. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-26 are hereby withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 8-26 are withdrawn from examination on the merits as these claims are directed toward a non-elected invention.

Claims 1-4 and 6-7 were examined on their merits.

Specification

The amendment filed 2/7/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The phrase '18.about.33 kHz' is new matter. Further, this amendment is not in proper format as Applicant has deleted/inserted/amended matter in the paragraph of the Specification without underlining and bracketing. Applicant is required to cancel the new matter in the reply to this Office Action.

The disclosure is objected to because of the following informalities:

First, Applicant has filed an amendment to the Specification wherein several grammatical errors were corrected (however, these amendments do not contain proper markings). The specification is replete with minor informalities such as grammatical and spelling errors. An example of such errors are the proposed corrections to the last paragraph of page 4 of the specification which states, in-part 'The inventor have spent

Art Unit: 1655

many years of investigation on nonlinear vibration, and inventor have disclosed....' and so-forth. Applicant is required to provide a new Specification which remedies these grammatical/idiomatic/spelling errors.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities:

Claim 1 recites 'comprises the flowing steps'; here, 'flowing' should properly recite 'following.' Claim 1 further recites 'obtaining a extract' which should properly recite 'obtaining an extract.'

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 remain rejected and claims 6-7 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement

Art Unit: 1655

for the reasons set forth on the record. It is noted that claims 6 and 7 should have been included in the previous rejection under this statute, however, were inadvertently omitted.

Applicant's arguments were fully considered, but not found persuasive.

Pertaining to this rejection, Applicant argues:

First, the subject matter in claims 1-4 is included in the originally filed application, at least in part, in the originally filed claims. "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." MPEP 2163(I) (A) (quoting *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)). The issue is whether a person skilled in the art would understand applicant to have invented, and been in possession of, the invention as broadly claimed. MPEP 2163(II)(A)(3)(a)(ii). Description requirement "does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." *Id.*...In the present case, the rejected claims cover a method applied to a Chinese traditional medicine or plant, not the genus of Chinese traditional medicine or plant itself. The claimed method includes such steps as crush, soaking and vibrating, which are well understood processes, at least individually and broadly. A person skilled in the art would understand applicant to have understood that such a method could be applied broadly to Chinese traditional medicine or plant. A person skilled in the art thus would understand applicant to have invented, and been in possession of the invention as claimed. (pp. 9-10. Remarks)

If the method was generically directed toward extraction of plants, Applicant's arguments may be persuasive. However, the method includes the extraction of 'active components' of Chinese traditional medicines or plants. Thus, Applicant claims, and wishes to patent a method for obtaining the active ingredient from all plants via the instantly claimed method. However, Applicant has only disclosed *one plant* which was extracted by a method similar to, but not exactly described in claims 1-4 and 6-7; that is, the specification describes that a particular apparatus is used to carry out the extraction

Art Unit: 1655

of an *Angelica sinensis* dried root material. While Applicant did not disclose a specific example in the Specification regarding the broad process as recited in claims 1-4 and 6-7 for extracting *Angelica sinensis*, it is accepted that the broad method steps (which may be carried out partly by hand, partly by machine), being similar to the use of an apparatus as disclosed, would provide for similar 'active ingredients.' Applicant has not described a representative number of extractions to indicate that the method as Instantly claimed will obtain 'active ingredients' from all plants and/or Chinese medicines. Further, while Applicant discloses that ferulic acid is present in *A. sinensis*, Applicant has not indicated that ferulic acid is present in all plants/Chinese traditional medicines. Thus, there is no predictive value present in the claims save for an extraction of *A. sinensis*; or in other words, the skilled artisan could not predictably extrapolate the Instantly claimed method to a representative number of plants and/or Chinese traditional medicines.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6-7 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'and then extracting.' This phrase lacks clear antecedent basis because it is not clear that the extraction is being carried out on the plant/medicine material. A means for overcoming this ambiguity is so state 'and then extracting said Chinese traditional medicine or plant...'.

Claim 1 recites 'Chinese traditional medicines.' The metes and bounds of this statement are not clearly delineated because the prior art has not absolutely ascertained what is included and/or excluded by 'Chinese traditional medicines.' For example, it can be said that many medicines which were 'traditionally used' in China are undocumented, and therefore the ordinary artisan could not readily ascertain if they were in fact infringing upon the claimed invention. Further, it is unclear if Applicant intends for 'Chinese traditional medicines' to include single plant material, combined plant material or extracts thereof. Further, does 'Chinese traditional medicines' read on materials other than plant material, such as snake which is a traditionally used medicine in China?

Claim 1 states 'obtaining a [sic] extract which contains the active components...'. Here, it is newly determined that the phrase 'active components' is indefinite. The metes and bounds of 'active' component cannot be delineated and therefore, the ordinary artisan would have trouble ascertaining if they were infringing upon the claimed

Art Unit: 1655

invention. What does Applicant intend for the term 'active' components' to mean? In essence, all molecules are 'active' in that they comprise atoms which are in constant movement. Does Applicant intend to mean that an active component is a component which is 'medicinally active'? Thus, the phrase is ambiguous and hence, indefinite. Correction is necessary.

Claim 1 recites '18~33' and '25~35', claim 2 recites '20 °C~ 50°C', claim 3 recites '1~3' and claim 4 recites '1:3~5.' These ranges are indefinite, because it is not understood exactly what Applicant intends for '~' to mean. In mathematics, this symbol means 'approximately equal to'; is this what Applicant intends for this symbol to mean, or does this mean 'about' or 'approximately'? The recitation of '~' in these claims rises to the level of ambiguity. Correction is necessary.

Claim 6 recites 'wherein said method further includes the step of carrying out the direct liquid package to the said extraction liquid.' This phrase lacks antecedent basis in claim 1 and the examiner cannot completely understand what Applicant intends for this statement to mean. What does 'carrying out the direct liquid package' mean? Because of the ambiguity of this claim language, the examiner cannot properly search this claim. This claim is treated as a non-limitation and is rejected with claims 1-4 and 7 under the same prior art rejection.

Claim 7 recites 'steps of the concentrating and drying the said extraction liquid' (emphasis added) which lacks antecedent basis in claim 1.

Claim Rejections - 35 USC § 103

Claims 1 and 3-4 remain rejected and claim 6 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,018,755) in view of Bloom (US 5,902, 224). The rejection of claim 5 over Wang is evidenced by Soinneae, P. (1997)*.

Applicant's arguments were fully considered, but not found persuasive.

Applicant argues that "...Wang only discloses performing sonication at a fixed frequency of 20KHz...." and not nonlinear vibration as Instantly claimed. However, it is deemed that even vibrations set at a fixed frequency will inherently have nonlinear vibrations as no linear system is perfect as synthesized, or as in nature. Absent any verifiable indications to the contrary, nonlinear vibrations are inherent to the disclosure of Wang.

Applicant further argues that "A combination of Wang and Bloom would result in, at most, sonicating the soybeans (without a high pressure) and then performing centrifugal sediment under a certain pressure" (page 10, Remarks). However, the

Art Unit: 1655

combined teachings of the prior art are adequate for making obvious the claimed invention because although Wang taught separate sonication and centrifugation steps, the Instantly claimed invention states 'comprising' which is open language and allows for the inclusion of unspecified, unclaimed steps. The entire extraction protocol as disclosed by Wang teaches that part of the extraction (upon sonication) occurs at a frequency within the range as Instantly claimed and that another part of the extraction occurs under pressure (upon centrifugation). Both steps occur in the overall extraction method. While, considering *arguendo*, Applicant may traverse the fact that centrifugation is not an extraction step, the Examiner's opinion is of the contrary. Centrifugation is a step which necessarily separates the solid part of the 'slurry' (plant matter admixed with solvent) from the liquid part of the slurry to obtain and thus 'extract' the liquid analyte fraction. Applicant does not specifically claim that the frequency and pressure must be applied simultaneously.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 1-4 remain rejected and claim 6 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,018,755) in view of Bloom (US 5,902, 224) in view of Yokotsuka et al. (US 4,064,277) for the reasons of record.

Applicant's sole traversal concerning this rejection mirrors the arguments as set forth in traversal over claims 1 and 3-4 remain rejected and claim 6 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,018,755) in view of Bloom (US 5,902, 224). The rejection of claim 5 over Wang is evidenced by Soinneae, P. (1997)*. Because those arguments are not persuasive, it follows that the arguments are also not persuasive for the same reasons set forth above.

Claims 1-4, 6 and 7 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,018,755) in view of Bloom (US 5,902, 224) in view of Yokotsuka et al. (US 4,064,277) in view of Thomas et al. (US 6,313,273 B1).

The teachings of Wang, Bloom and Yokotsuka et al. were keenly discussed in the previous Office action. None of the references specifically taught concentration/drying the extract.

Concentration and drying extracts comprising soy proteins was routine in the art. Thomas et al. (US 6,313,273 B1) for example, discloses a method for purifying soy

Art Unit: 1655

proteins via extraction and subsequent concentration and freeze drying (freeze drying includes concentrating and drying –concentrating in the sense that they are removing water) the resultant liquid protein-containing extract for later analysis.(see Examples 3 and 4, column 15).

One of ordinary skill in the art would have been motivated to freeze dry the resultant supernatant (protein-containing extract) of Wang in order to suitably store the protein extract for further use and allotment/aliquoting.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655
April 16, 2008

Application/Control Number: 10/580,061
Art Unit: 1655

Page 15